K081127 #1/2

OCT 17 2008

Summary of Safety and Effectiveness

Submitter: Michael Kvitnitsky
Accelerated Innovation, LLC
1033 US Highway 46, Suite A204
Clifton, NJ 07103

Date Prepared: April 18, 2008

Device: Accin™ total knee system

Classification: 87 JWH – Prosthesis, Knee, Patellofemoraltibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer - Class II (21 CFR 888.3560)

Predicate Device:
- Osteonics® Scorpio Posteriorly Stabilized Total Knee System (K962152)
- Osteonics® Scorpio Posterior Cruciate Retaining Total Knee System (K974556)
- Zimmer NexGen® Complete Knee Solution *Legacy*® Posterior Stabilized (LPS); LPS-Flex Fixed Bearing Femoral and Articular Surface Components (K991581)

Device Description: The Accin™ total knee system consists of a series of cobalt chrome femoral components, a series of cobalt chrome tibial tray components and a series of UHMWPE modular tibial bearing components.

Intended Use: The ACCIN Total Knee System components are for use in total knee arthroplasty as a result of:

- Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis;
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
- Revisions of previous unsuccessful knee replacement or other procedure.

Additional indications for posteriorly stabilized components:

- Ligamentous instability requiring implant bearing surfaces with increased constraint;
- Absent or non-functioning posterior cruciate ligament.

These devices are single use only and are intended for implantation with bone cement.

Comparison to Predicates:
The Accin™ total knee system consists of a series of cobalt chrome femoral components, a series of cobalt chrome tibial tray components and a series of UHMWPE modular tibial bearing components. The system is similar to the Osteonics Scorpio® Posteriorly Stabilized Total Knee System, the Osteonics Scorpio® Posterior Cruciate Retaining Total Knee System and the Zimmer LPS-Flex Fixed Bearing Femoral and Articular Surface Components. The trochlear region of the femoral component is designed to articulate with the Accin™ patellar component, previously approved under K073120. The predicate systems and the proposed system are both for use in total knee replacement surgery. Both the predicate systems and the proposed system have femoral components made from cobalt chrome and modular tibial bearing components made from UHMWPE. Both the predicate Scorpio Total Knee System and the proposed system have cobalt chrome tibial tray components.

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Accelerated Innovation, LLC has determined that the minor differences in the proposed device will not impact the safety or effectiveness of the total knee system for its intended use. Analysis has shown that the proposed device is equivalent to the predicate devices.

Synopsis of Test Methods and Results:
Numerous tests were performed on the Accin™ total knee system. The tests performed can be found in the FDA guidance documents on total knee arthroplasty devices and ASTM Standards F1800, F2083 and F1223. Testing has shown that the Accin™ total knee system meets the requirements of the current FDA Guidance documents on total knee arthroplasty product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2008

Cardo Medical Corporation
% Mr. Michael Kvitnitsky
1033 US Highway 46 East, Suite A204
Clifton, New Jersey 07103

Re: K081127
Trade/Device Name: ACCIN Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer
Regulatory Class: Class II
Product Code: JWH
Dated: October 09, 2008
Received: October 10, 2008

Dear Mr. Kvitnitsky

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K081127

Device Name: Accin™ total knee system

Indications for Use:

The ACCIN Total Knee System components are for use in total knee arthroplasty as a result of:

- Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis;
- Post-traumatic loss of knee joint configuration and function
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These devices are single use only and are intended for implantation with bone cement.

Prescription Use ___X___ (Per 21 CFR 801.109) OR Over-The-Counter Use_____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081127